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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/896,509	06/28/2001	Hiroaki Shizuya	CIT1390-1	8122

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EXAMINER

MARVICH, MARIA

ART UNIT	PAPER NUMBER
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1636

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DATE MAILED: 06/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/896,509

Applicant(s)

SHIZUYA, HIROAKI

Examiner

Maria B Marvich, PhD

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 March 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-55 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1, 3-6 and 9-24 is/are allowed.
- 6) ☒ Claim(s) 2,25,27 and 29 is/are rejected.
- 7) ☐ Claim(s) 8,26-28 and 30-55 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 March 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

This office action is in response to an amendment filed 3/14/03. Claims 1, 2, 24, 43, 46, 47 and 55 have been amended. No claims have been added or cancelled. Claims 1-55 are pending in this application.

Response to Amendment

The objection to the drawings has been withdrawn in light of newly submitted figures that have been approved by the Draftsman.

The objection to the abstract of the disclosure is withdrawn as it has been amended to define BAC.

Rejection of claims 25 and 55 under 112, second paragraph, for use of the phrase "a corresponding essential gene" is withdrawn in light of amendment to claims. Specifically, "corresponding" has been deleted.

Rejection of claims 46-48 under 112, second paragraph, is withdrawn in light of amendment to claims. Specifically, the claims have been drafted to omit reference to the host cell and replace it with "test cell" which has antecedence in claim 43.

Rejection of claims 2, 25 and 43 under 112, second paragraph, is withdrawn in light of amendment to claims. Specifically, the missing steps have been added to the claims.

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Rejection to claims 1-12, 14-34, 36-45, 47 and 49-55 under 35 U.S.C. 112, first paragraph, has been withdrawn in light of applicant's arguments. Specifically, it is pointed out that the host cell must be a haploid host cell whose genome is known and which is capable of being transformed and of undergoing DNA recombination. Therefore, the invention is enabling as regards use of any host cell meeting these requirements. Furthermore, these characteristics provide a correlation between structure-function.

Specification

The disclosure is objected to because of the following informalities: Table 1 and the corresponding text have many inconsistencies. The descriptions in paragraph [0064] do not match the actual table and the text within the table is not consistent with the diagrams. **For example**, F describes a transposon in BAC and yet the diagram does not show this. The text states that F and E differ in their growth at 43°C without drugs and yet they actually differ in their growth at 43°C with kanamycin. As another example D and E are designated as constructs in which BAC is outside the essential gene and yet it appears that BAC is **in** an essential gene according to the diagram and in the text D is described as containing a transposon in a non-essential gene.

Claim Objections

Claims 43 and 55 are objected to because of the following informalities: Claim 43, line 9 recites into the a haploid cell. Claim 55, line 1 recites "a essential gene" and should recite "an essential gene" Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2, 7, 25 and 29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 7 and 29 are unclear for reciting that the "resistance genes are selected to provide resistance to the group consisting of". As written, the claim states that resistance must be to all of the following antibiotics. It is unclear whether applicant means that resistance to all antibiotics or to one or some of the group is required.

Claims 1 and 3-6, 9-24 are allowed.

Claims 43-55 are objected to.

Claims 2, 7, 25 and 29 are rejected.

Claims 8, 26-28 and 30-42 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria B Marvich, PhD whose telephone number is (703) 605-

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1207. The examiner can normally be reached on M-F (6:30-3:00). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, PhD can be reached on (703) 305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 305-4242 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the patent analyst, Zeta Adams, whose telephone number is (703) 305-3291.

Maria B Marvich, PhD
Examiner
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June 2, 2003

DAVID GUZO
PRIMARY EXAMINER
